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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/485,163	06/07/1995	GARY A. BEAUDRY	37690-II-I-P	5331

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EXAMINER

GAMBEL, PHILLIP

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/485,163

Applicant(s)

BEAUDRY ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/6/02; 11/13/02; 12/1/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Phillip Gambel, Group Art Unit 1644.

2. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.129(a).

Applicant's second submission after final, filed on 6/6/02, has been entered.

Applicant's amendment, filed 6/6/02, has been entered.

Claims 30-35 and 44-46 have been canceled. Claims 1-29 and 36-43 have been canceled previously. Claims 47-55 have been added.

Applicant's amendment, filed 11/13/02, has been entered.

Claims 54-55 have been amended.

Claims 47-55 are pending.

2. Applicant's amendment, filed 11/13/02, appears to have placed the instant application in compliance with the sequence rules for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the TM or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

It is noted that the instant specification that has been scanned into Image File Wrapper (IFW) has numerous errors in the omission of letters and words (e.g. see the entire specification, including page 4, lines 1-2; page 21, lines 1-2; page 22, lines 1-2, etc. etc. etc.).

A substitute specification is required because the numerous entries would be needed to amend the specification to account for all of the missing letters and words in the current scanned specification.

The substitute specification filed must be accompanied by a statement that it contains no new matter.

Such statement must be a verified statement if made by a person not registered to practice before the Office.

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Applicant should update the status of the priority documents on the first line of the specification.

The examiner apologizes for any inconvenience in this matter.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 47-55 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

“at least one vector” recited in claim 47, lines 2 and 4,
“mammalian cell” recited in claim 48 and
“COS cell, a CHO cell or a myeloma cell” recited in claim 49.

Applicant's amendment, filed 6/3/02, directs support to pages 12 and 27-29 for claim 47 and page 21 for claim claims 48-49 for the written description of the “limitations”.

However, the specification as filed does not appear to provide sufficient written description for the generic recitation of the claimed “at least one vector”, mammalian cell, “COS cell, a CHO cell or a myeloma cell”.

There does not appear to be a written description of “at least one vector”, including “at least one vector” in the context of the claimed transformed host cells.

While the specification provides for specific examples of mammalian cell lines, including specific COS, CHO and myeloma cell lines, there appears insufficient written description for the genus comprising cells, COS cells, CHO cells and myeloma cells, as currently encompassed by the claimed invention.

The claims represent a departure from the specification and claims as originally filed. Applicant's reliance on generic disclosure and possibly certain limited species does not provide sufficient direction and guidance to broadly claim generic “limitations”, as currently recited.

The instant claims are drawn to new matter since they broadly recite different genres which are not disclosed in original application as filed, which discloses certain specific vectors as well as number of vectors (versus “at least one”) and certain cell lines (versus “cells”).

Also, see In re East and Harmon (CCPA) 181 USPQ 716 (May 9, 1974) and MPEP 2163.05 (I).

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The specification does not provide sufficient blazemarks nor direction for broadly claiming "at least one vector" and "cells", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

7. Upon reconsideration of applicant's newly added claims in conjunction with applicant's amendment, including arguments and Exhibits, filed 6/6/02; it appears that the specific structure of the vectors comprising nucleic acids encoding CD4-IgG2 chimeric heterotetramers in the claimed transformed host cells appears free of the prior art.

Applicant's arguments and Exhibits are the same or nearly the same with respect to the structural distinctions and unexpected results associated with the claimed CD4-IgG2 chimeric heterotetramers limitations as presented in related U.S. Patent No. 6,451,313, as acknowledged by applicant's amendment, filed 6/6/02.

8. No claim allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
April 14, 2005